

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: JOHNSON & JOHNSON
TALCUM POWDER PRODUCTS
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

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) MDL Docket No. 2738
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This Document Relates To All Cases

**DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON
CONSUMER INC.'S MEMORANDUM OF LAW IN SUPPORT OF
CONDITIONAL MOTION TO EXCLUDE CERTAIN PLAINTIFFS'
EXPERTS' OPINIONS FOR LACK OF QUALIFICATIONS**

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The key, overarching question at this stage of the litigation is whether there is reliable science that perineal use of cosmetic talcum powder can cause ovarian cancer. To address that question, both plaintiffs and defendants have retained a slate of experts to offer opinions related to the issue of general causation, every one of whom is an M.D. or Ph.D. in various fields, such as gynecologic oncology, epidemiology/biostatistics, pathology, cancer biology or toxicology. In light of the experience of the experts on both sides and the complexities of the scientific issues in this litigation, the J&J defendants believe that it would be a waste of time and resources for the parties and the Court to spend a significant amount of energy debating whether the parties' experts are qualified to offer the opinions in their reports. This is especially true because the experts for both parties are trained and experienced in overlapping fields – such that any qualifications challenge to one party's experts would apply equally to witnesses on the other side as well. Moreover, as detailed in the J&J defendants' various memoranda in support of their omnibus motion to exclude plaintiffs' experts' opinions, none of plaintiffs' experts has a reliable methodological basis for connecting talc use to ovarian cancer, and a host of other causation-related opinions that they seek to offer are similarly unsupported by the relevant science. These fundamental deficiencies require exclusion of plaintiffs' experts' opinions regardless of their qualifications.

Moreover, the Third Circuit has made clear that it “interpret[s] Rule 702’s qualification requirement liberally,” recognizing that a “broad range of knowledge, skills, and training qualify an expert.” *Pineda v. Ford Motor Co.*, 520 F.3d 237, 244 (3d Cir. 2008) (citation omitted); *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594 (D.N.J. 2002) (noting that the Third Circuit has “eschewed imposing overly rigorous requirements of expertise and [has] been satisfied with more general qualifications”), *aff’d*, 68 F. App’x 356 (3d Cir. 2003). As a result, “most arguments about an expert’s qualifications relate more to the weight to be given the expert’s testimony than to its admissibility.” *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 782-83 (3d Cir. 1996) (rejecting argument that board-certified physician in internal and pulmonary medicine was unqualified to testify about the causes of mesothelioma).

Nonetheless, in anticipation of plaintiffs’ qualification challenges with respect to defendants’ experts, the J&J defendants respectfully submit this briefing to address plaintiffs’ experts’ qualifications. In particular, and as set forth in more detail below, many of plaintiffs’ experts seek to offer opinions on a wide range of subjects that fall outside the scope of their expertise and – in a number of cases – expressly admitted as much at their depositions. Defendants thus conditionally move to exclude the opinions of these experts in part or in full based on lack of

relevant qualifications to the extent the Court considers plaintiffs' motions related to qualifications.

I. ARCH CARSON

Dr. Carson, a physician who "specializes in the practice of medical toxicology,"¹ seeks to offer a variety of opinions in this litigation that are grounded in epidemiology,² even though he is not an epidemiologist and did not train in epidemiology.³ Not only does Dr. Carson lack epidemiological expertise, but he is also not a gynecologist or an oncologist; has never treated women for gynecological cancer; is not a cancer biologist; and has never been involved in

¹ (Expert Report of Arch Carson, M.D., Ph.D. ("Carson Rep.") ¶ 2, Nov. 16, 2018 (attached as Ex. C9 to Tersigni Cert.)) Medical toxicology is a subspecialty of medicine that focuses on the diagnosis, treatment and prevention of poisoning and other adverse effects due to medications, occupational and environmental toxicants and biological agents. In other words, a medical toxicologist focuses on the clinical management of patients who have been exposed to poisons or other toxic substances. By contrast, a scientist with a Ph.D. in toxicology focuses on analyzing the nature, effects and detection of poisons and other toxic substances.

² (*Id.* at 9.)

³ (Dep. of Arch I. Carson, M.D., Ph.D. ("Carson Dep.") 61:17-19, Jan. 19, 2019 (attached as Ex. B5 to Tersigni Cert.)) Plaintiffs questioned defendants' experts extensively regarding whether they had expertise in the area of epidemiology, suggesting they intend to take a narrow view of what qualifies someone to opine on this topic. (*See, e.g.*, Dep. of Ie-Ming Shih, M.D., Ph.D. 52:11-54:24, Mar. 26, 2019 (attached as Ex. B28 to Tersigni Cert.) (plaintiffs' counsel asking Dr. Shih, a gynecologic pathologist, about his experience in the field of epidemiology); Dep. of H. Nadia Moore, Ph.D. ("Moore Dep.") 127:21-128:4, Apr. 4, 2019 (attached as Ex. B27 to Tersigni Cert.) (plaintiffs' counsel asking Dr. Moore, a toxicologist, about her experience in the field of epidemiology).)

research relating to ovarian cancer.⁴ Dr. Carson also has never published anything regarding talcum powder specifically,⁵ an issue plaintiffs’ counsel repeatedly raised in depositions of defendants’ experts who seek to provide epidemiological and other opinions.⁶ Nonetheless, he purports to undertake a Bradford Hill analysis of the alleged causal connection between talc and ovarian cancer in his report.⁷

Other opinions offered by Dr. Carson similarly fall outside of his area of expertise, including those regarding the purported contamination of talc with asbestos, heavy metals, fibrous talc and fragrances and the supposed causal relationship between these substances and ovarian cancer.⁸ Dr. Carson testified that it is his “opinion that *all* talcum powder products do contain a certain amount

⁴ (*Id.* 60:11-62:20.)

⁵ (*Id.* 64:9-11.)

⁶ (*See, e.g.*, Dep. of Christian Merlo, M.D., M.P.H. (“Merlo Dep.”) 25:13-16, Apr. 18, 2019 (attached as Ex. B9 to Tersigni Cert.) (plaintiffs’ counsel asking whether he “published a commentary or review on talcum powder products and its [sic] safety”); Moore Dep. 155:17-19 (plaintiffs’ counsel asking, “Have you ever published on anything pertaining to talc?”); Dep. of Michael Birrer, M.D., Ph.D. 102:2-8, Mar. 29, 2019 (attached as Ex. B36 to Tersigni Cert.) (plaintiffs’ counsel asking, “You’ve never published an article on talcum powder and ovarian cancer? Is that correct?”); Dep. of Karla Ballman, Ph.D. 49:20-50:6, Mar. 22, 2019 (attached as Ex. B32 to Tersigni Cert.) (plaintiffs’ counsel asking whether she had “ever expressed an opinion” on talc and ovarian cancer before this litigation).)

⁷ (*See* Carson Rep. at 8-11.)

⁸ (*Id.* at 5.)

of asbestos, even if it's extremely small.”⁹ He pressed those opinions in the face of his disclaimer of any expertise with regard to asbestos and notwithstanding the fact that he is *not* a geologist or a mineralogist.¹⁰ Dr. Carson's claim that heavy metals, fibrous talc and added fragrances contribute to talcum powder's cancer-causing potential is similarly beyond his expertise, by his own admission.¹¹ Indeed, Dr. Carson's lack of qualifications to address these topics is evident from the fact that he relies entirely on another of plaintiffs' experts – Dr. Michael Crowley – to support his opinions on them.¹² In short, much of Dr. Carson's report consists of opinions that stray well outside the confines of his expertise as a medical toxicologist.

II. ROBERT COOK

Dr. Cook is a mining engineer and geologist¹³ who was retained “to review the geology of the talc deposits that sourced Defendants' talcum powder products, to evaluate the mining practices employed, and to assess Defendants' sampling and

⁹ (Carson Dep. 353:20-23 (emphasis added).)

¹⁰ (See *id.* 55:15-20 (“I don't consider myself an asbestos expert.”); *id.* 61:2-4 (testifying that he is not a geologist, mineralogist or microscopist).)

¹¹ (See *id.* 64:12-21 (admitting he has never researched fragrances); 137:11-13 (“Q. Do you consider yourself to be an expert on fibrous talc? A. No, I don't.”).)

¹² (See Carson Rep. at 6-8.)

¹³ (Dep. of Robert Cook, Ph.D. (“Cook Dep.”) 69:17-70:7, Jan. 30, 2019 (attached as Ex. B43 to Tersigni Cert.).)

testing from a mining perspective.”¹⁴ Dr. Cook’s opinions go well beyond the scope of his claimed expertise as a mining engineer and geologist. For example:

- Dr. Cook contends that “[t]alc deposits derived by the alteration of serpentinites contain chrysotile and amphibole species in fibrous asbestiform habits, all of which are known carcinogens”;¹⁵
- Dr. Cook asserts that “[f]ibrous talc occurs in serpentinite-derived talc deposits, possibly by pseudomorphism of early chrysotile or amphiboles. Such fibrous talc is not detectable by standard amphibole asbestos XRD screening . . .”;¹⁶
- Dr. Cook opines that “[m]ine development and selective mining are not completely effective in avoiding ore and ore-related rock potentially containing amphiboles, chrysotile, and elevated amounts of heavy metals and arsenic”;¹⁷ and
- Dr. Cook states that “[a]nalytical data indicate that nickel, chromium and cobalt, known carcinogens, reach finished talc products in amounts above

¹⁴ (Am. Expert Report of Robert B. Cook, Ph.D. (“Am. Cook Rep.”) at 2, Jan. 22, 2019 (attached as Ex. C2 to Tersigni Cert.).)

¹⁵ (*See id.* at 2.)

¹⁶ (*Id.*)

¹⁷ (*Id.*)

Johnson & Johnson's (J&J) specified limits.”¹⁸

Dr. Cook is not qualified to offer these opinions. Dr. Cook has repeatedly conceded that he is not an expert in carcinogenicity or toxicology.¹⁹ Nor has he published anything regarding talcum powder specifically.²⁰ And prior to being retained as an expert in this MDL proceeding, Dr. Cook had not even “thought about the . . . talc-ovarian cancer issue at all,”²¹ let alone formulated any opinions with respect to the potential presence “of asbestos or heavy metals in talcum powder.”²² Accordingly, the Court should bar Dr. Cook from offering opinions in these areas that, by his own admission, stray well beyond his areas of expertise.

¹⁸ (*Id.* at 3; *see also, e.g., id.* at 2 (stating that “chrysotile and amphibole species in fibrous asbestiform habits” and “[f]ibrous talc” “are known carcinogens”); *id.* at 3 (opining “that nickel, chromium and cobalt” are “known carcinogens”); *id.* at 4 n.3 (stating that asbestos is “a human carcinogen”); *id.* at 9 (stating that “fibrous talc . . . has been determined to have similar harmful effects as asbestos”); *id.* at 29 (“Arsenic is a known human carcinogen.”); *id.* at 42 (concluding “talc deposits . . . contain[] . . . known carcinogens”).)

¹⁹ (Cook Dep. 70:12-71:3, 95:17-96:8 (agreeing that “we’ve already determined you’re not an expert. You know, you’re not a doctor. You’re not a toxicologist.”); *id.* 96:20-22 (agreeing that “[he’s] not here to, you know, opine what may or may not cause human disease”); *id.* 99:14-18, 222:13-15 (“You’re not a toxicologist; right? A. Right.”); *id.* 314:7-13 (“Human disease I’m not an expert in.”); *id.* 397:2-16, 402:3-10 (“I’m not an expert in human disease.”); *id.* 441:17-442:1 (agreeing he “[is] not an expert on toxicology . . . or carcinogenicity or medicine”).)

²⁰ (*Id.* 29:6-10.)

²¹ (Cook Dep 29:6-10.)

²² (*Id.* 88:4-10.)

III. MICHAEL CROWLEY

Dr. Crowley, a chemist, was retained to address two questions: (1) whether the fragrance chemicals in defendants' talcum powder products are compliant with governmental and industry standards; and (2) whether such alleged chemicals can "contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products."²³ Dr. Crowley lacks the requisite expertise to answer these fundamental questions.

First, Dr. Crowley's own deposition testimony reveals that he is *not* an expert on FDA regulations. Specifically, the extent of his knowledge and experience with this wide-ranging topic is that he "read" and "understand[s]" FDA regulations.²⁴ He nonetheless seeks to opine that the fragrance components of Johnson & Johnsons Consumer Inc.'s ("JJCI's") talcum powder products "are not in compliance with governmental and industry standards."²⁵ Dr. Crowley's mere reading and understanding of FDA regulations should not suffice to qualify him as an expert in FDA or industry standards, particularly given that his stated "methodology" for reaching his ultimate conclusion was taking a list of fragrance chemicals provided in the report of Thomas Dydek (one of plaintiffs' state court

²³ (Expert Report of Michael M. Crowley, Ph.D. ("Crowley Rep.") at 11, Nov. 12, 2018 (attached as Ex. C34 to Tersigni Cert.).)

²⁴ (Dep. of Michael Crowley, Ph.D. ("Crowley Dep.") 61:20-23, Jan. 4, 2019 (attached as Ex. B37 to Tersigni Cert.).)

²⁵ (Crowley Rep. at 11.)

experts) and then “plugging” the “names of the chemicals” into “Google or PubChem to see what [he] could find.”²⁶ *See Craig v. Xlear, Inc.*, No. 2:16-cv-00392-DB-EJF, 2019 WL 1119429, at *6 (D. Utah Mar. 11, 2019) (expert was unqualified to offer opinions regarding breach of fiduciary duty where he had to conduct Google searches to understand the definition of that term); *Huffman v. Electrolux Home Prods., Inc.*, 129 F. Supp. 3d 529, 539 (N.D. Ohio 2015) (finding expert unqualified to opine on presence of mold in washing machines where expert had never investigated mold prior to preparing his report and limited his investigation to internet research).

Second, Dr. Crowley’s deposition testimony similarly demonstrates that he is not sufficiently qualified to opine about the putative capacity of the alleged fragrance chemicals in talcum powder products to “contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products.”²⁷ In particular, as Dr. Crowley admitted, he has never written or published papers on the topics of fragrance chemicals or talcum powder or addressing the question of talcum powder and purported inflammation or irritation.²⁸ He also made it clear that he is not a medical toxicologist, doctor, or pathologist, and he does not have a Ph.D. in toxicology; nor, as it relates to this litigation more specifically, does he have any

²⁶ (Crowley Dep. 109:7-12.)

²⁷ (Crowley Rep. at 11.)

²⁸ (Crowley Dep. 65:5-8, 66:18-67:8.)

prior experience in perineally-applied cosmetic products or with fragrance chemicals, asbestos, ovarian cancer, inflammation or irritation as it relates to talcum powder.²⁹ Yet, Dr. Crowley’s opinions about the supposed capacity of the alleged fragrance chemicals in talcum powder products to contribute to the inflammatory properties, toxicity, and potential carcinogenicity of the products indisputably reached these specialized matters. Indeed, Dr. Crowley repeatedly addresses such varied matters as epidemiology and biological plausibility (including the subsidiary issues of migration, inflammation and oxidative stress).

For example, Dr. Crowley claims that: (1) epidemiology supports the conclusion that the fragrances in talc can cause or increase the risk of cancer;³⁰ (2) certain fragrances “can cause inflammation and oxidative stress” and, correspondingly, contribute to the alleged “potential carcinogenicity” of Johnson’s Baby Powder and Shower to Shower;³¹ (3) inflammation causes “insults to the vagina” that “generate certain proteins” that have “been positively linked with higher incidences of cancers in the . . . female reproductive organs”;³² and (4) skin irritation can somehow cause ovarian cancer because “inflammatory chemicals

²⁹ (*Id.* 55:16-24, 62:10-67:21.)

³⁰ (*Id.* 106:15-107:8.)

³¹ (Crowley Rep. at 14; *see also id.* at 65 (similar).)

³² (Crowley Dep. 216:18-217:10.)

travel throughout the human body.”³³ None of these topics falls within even Dr. Crowley’s aggressive definition of his own expertise. Because Dr. Crowley is not qualified to offer opinions regarding FDA regulations, cancer biology, industry standards and the presence and alleged health effect of fragrance chemicals in defendants’ talcum powder products, those opinions should be excluded.

IV. SARAH KANE

Dr. Kane is a pathologist who “offers opinions in a host of areas outside her field, including epidemiology and cancer biology.”³⁴ As Dr. Kane acknowledged, she is not an epidemiologist; she does not have a degree in epidemiology; she has never designed or published an epidemiological study; and she has never taught a course in epidemiology.³⁵

Nevertheless, Dr. Kane’s report undertakes a study-by-study analysis, offering a paragraph for each of several epidemiological studies in a discussion that spans from page 16 to page 29 of her report. These lengthy overviews of the literature conclude with (largely unreferenced) discussions of the strengths and weaknesses of each of these studies, including on matters such as recall bias and confounders; the strength and consistency of the epidemiological associations; and

³³ (*Id.* 82:4-83:3.)

³⁴ (Expert Report of Robert J. Kurman at 12, Feb. 25, 2019 (attached as Ex. C37 to Tersigni Cert.).)

³⁵ (Dep. of Sarah E. Kane, M.D. (“Kane Dep.”) 223:18-226:1, Jan. 25, 2019 (attached as Ex. B45 to Tersigni Cert.).)

the likely means by which the studies were administered (e.g., the use of trained interviewers, the blinding of study participants, and the like).³⁶ While Dr. Kane insisted at her deposition that she “review[s] epidemiology and critique[s] epidemiology studies on a regular basis in [her] daily practice,”³⁷ that does not qualify her to make the sort of in-depth judgments she offers about the particulars of the designs, strengths and weaknesses of individual studies.

Dr. Kane also ventures into other areas clearly outside her expertise. She admitted at her deposition, for example, that she is not an asbestos expert.³⁸ But in her report, she offers the opinion that “[t]he morphologic and immunohistochemical similarities between asbestos and talc malignancies constitute another line of evidence supporting my opinion that talc exposure in the genital area causes ovarian cancer.”³⁹ She also opines that she has “seen evidence that talcum powder products manufactured by Johnson & Johnson (J&J Baby Powder and Shower to Shower) contained and continue to contain asbestos, talc containing asbestiform fibers (e.g. talc occurring in a fibrous habit) heavy metals (such as cobalt, chromium, nickel) and fragrance chemicals.”⁴⁰ But Dr. Kane

³⁶ (E.g., Expert Report of Sarah Kane (“Kane Rep.”) at 23, Nov. 15, 2018 (attached as Ex. C38 to Tersigni Cert.).)

³⁷ (Kane Dep. 214:11-16.)

³⁸ (*Id.* 321:21-322:3.)

³⁹ (Kane Rep. at 14.)

⁴⁰ (*Id.* at 29.)

avowedly lacks the expertise to independently evaluate the evidence she claims to “have seen” along these lines, and accordingly, she should not be allowed to offer an opinion on the matter.

V. MARK KREKELER

Dr. Krekeler classifies himself as an expert in the area of mineralogy,⁴¹ but he far exceeds the scope of his expertise by offering opinions on topics as to which he has no special knowledge or training, including mining standards, health effects and carcinogenicity of various substances and regulatory processes.

Most notably, Dr. Krekeler’s bottom line – that crushed-up nonasbestiform cleavage fragments pose a health risk – is well beyond his expertise. After all, Dr. Krekeler is a geologist, not a medical doctor or epidemiologist.⁴² As a result, he relies solely on “documents and things [he’s] read” by specialists in those fields to reach this “opinion.”⁴³ This is no substitute for relevant expertise. Accordingly, Dr. Krekeler’s opinion on the health effects of cleavage fragments should be excluded.

⁴¹ (See Dep. of Mark Krekeler, Ph.D. (“Krekeler Dep.”) 16:15-17, Jan. 25, 2019 (attached as Ex. B34 to Tersigni Cert.).)

⁴² (*Id.* 25:6-10 (“Q. Okay. And you’re not going to render any opinions about what causes disease, anything of that nature? A. Correct. I am not a medical expert. I am not an environmental health expert.”).)

⁴³ (*Id.* 114:17-20.)

Moreover, although Dr. Krekeler admitted that he is “not an expert in the molecular mechanism of carcinogenicity” and “not a medical person,”⁴⁴ he repeatedly refers to various contaminants as “toxic”⁴⁵ and opines on the alleged health risks of talc, asbestos and nonasbestiform fibers.⁴⁶ Similarly, Dr. Krekeler concedes that he is not “qualified to opine as to whether or not a particular level of nickel,” “arsenic, . . . cobalt and . . . chromium” “is sufficient to cause human disease,”⁴⁷ but still purports to offer opinions on the health risks of these materials.⁴⁸ These medical opinions are concededly beyond Dr. Krekeler’s expertise.

Dr. Krekeler also goes beyond his expertise as a mineralogist by attempting to offer opinions pertaining to federal and international regulatory standards.

⁴⁴ (*Id.* 25:6-22; *see also id.* 45:19-46:1 (admitting he is “not a medical doctor” and “not a toxicologist”); *id.* 115:11-22, 181:15-20 (“I’m not a medical expert”); 269:18-23 (“I am not an oncologist. I am not a medical expert.”); 271:7-16 (“I’m not a medical expert.”).)

⁴⁵ (Expert Report of Mark Krekeler, Ph.D. (“Krekeler Rep.”) at 1, Nov. 16, 2018 (attached as Ex. C31 to Tersigni Cert.) (describing constituents as “toxic”); *id.* at 6 (explaining “[m]ost heavy metals are toxic”).)

⁴⁶ (*Id.* at 4 (opining that “nonasbestiform cleavage particles . . . can have potentially dangerous health effects”); *id.* at 6-7 (opining that “[a]cademic and research literature have long-recognized many toxic metals commonly found in talc as known or possible carcinogens”); *id.* at 14 (opining that the “presence of fibrous talc [is] of significant concern from a human health . . . standpoint”).)

⁴⁷ (Krekeler Dep. 274:9-23, 279:16-25.)

⁴⁸ (*See, e.g.,* Krekeler Rep. at 6-7 (listing chromium, nickel, cobalt and arsenic as “known or possible carcinogens”); *id.* at 33 (“Arsenic is a known human carcinogen.”); *id.* at 34 (“Nickel is a known human carcinogen.”).)

Dr. Krekeler admits that he is “not an expert in regulatory processes or mine regulations.”⁴⁹ Nevertheless, he seeks to offer a host of opinions that JJCI’s mining practices – and the resulting JJCI cosmetic talc products – fail to satisfy regulatory standards.⁵⁰ Because he has no specialized knowledge on these topics, these expert opinions are improper.

VI. SHAWN LEVY

Shawn Levy, who has a Ph.D. in biochemistry, has been “retained to describe the role of genetics in the pathogenesis of cancer in general and specifically ovarian cancer.”⁵¹ But his opinions regarding biological plausibility clearly exceed his expertise and should be excluded for lack of qualifications to the extent the Court entertains plaintiffs’ expertise-based challenges.

Dr. Levy’s expertise generally pertains to genetics associated with specific health conditions – e.g., head and neck cancer, breast cancer and hepatosplenic

⁴⁹ (Krekeler Dep. 46:2-4; *see also id.* 211:4-7 (similar); *id.* 223:13-16 (“I’m not a regulatory expert.”); *id.* 234:13-21 (same).)

⁵⁰ (*See, e.g.,* Krekeler Rep. at 37 (opining “Johnson & Johnson’s baby powder and Shower to Shower products contained excessive levels of cobalt . . . by federal standards”); *id.* at 12 (opining that “[t]he practices and procedures Defendants tout fall short of satisfying international standards of quality and purity”); *id.* at 33 (opining that “arsenic levels [are] well above international and national health standard regulation”); *id.* at 36 (explaining that “[t]he EPA, NIOSH and OSHA have established maximum safe levels for human consumption”).)

⁵¹ (Expert Report of Shawn Levy, Ph.D. (“Levy Rep.”) at 2, Nov. 16, 2018 (attached as Ex. C39 to Tersigni Cert.).)

T-cell lymphoma.⁵² He has very little experience with ovarian cancer and has even less (indeed, zero) experience with talc, or with any of the substances that he claims contaminate cosmetic talc products, including asbestos, fibrous talc, metals and fragrances. In particular, Dr. Levy admits that the focus of his practice is not ovarian cancer,⁵³ and he has published just a single article regarding that topic during the course of his entire career.⁵⁴

It is therefore hardly surprising that, in reaching his conclusion that talcum powder leads to biological changes that cause ovarian cancer, Dr. Levy was heavily reliant on *others'* opinions, particularly with respect to epidemiology.⁵⁵ Nonetheless, Dr. Levy does seek to opine that “there’s a clear and well-evidenced biologically plausible role for talcum powder leading to ovarian cancer.”⁵⁶ He further offers an opinion that asbestos, fibrous talc, metals and fragrances compound the purported inflammatory and carcinogenic effect of talc.⁵⁷ But he conceded that he did not conduct any formal testing of his theory of biological

⁵² (*Id.* at 2.)

⁵³ (*See* Dep. of Shawn Levy, Ph.D. (“Levy Dep.”) 90:3-8, Jan. 11, 2019 (attached as Ex. B46 to Tersigni Cert.).)

⁵⁴ (*Id.* 19:17-19.)

⁵⁵ (*Id.* 233:10-15 (“I would refer to and defer to the other experts in epidemiology regarding their opinions on the validity of the asso[ciation]—validity and strength of the associations, again, from a formal epidemiology perspective.”).)

⁵⁶ (*Id.* 112:6-9.)

⁵⁷ (Levy Rep. at 15-17.)

plausibility – i.e., that “the more biologically active compounds you have in an exposure such as talc plus asbestos plus chromium and then plus a milieu of chemicals that are in fragrances may have an amplification effect.”⁵⁸ Nor could he point to a particular article or any published scientific support for that theory. These shortcomings illustrate Dr. Levy’s fundamental lack of expertise with regard to the purported biological changes that allegedly occur as a result of talcum powder use. Accordingly, if the Court considers qualification challenges, his opinions must be limited.

VII. ANNE MCTIERNAN

Dr. McTiernan is an epidemiologist and doctor of internal medicine who was retained to “review the current state of the scientific literature regarding talcum powder products and opine on whether those products cause ovarian cancer.”⁵⁹ Dr. McTiernan has not published any articles on the causes of ovarian cancer and did not reach a conclusion that perineal talc use causes ovarian cancer until she “began this project with Counsel.”⁶⁰ Thus, to the extent plaintiffs challenge any of defendants’ experts on grounds that they do not have a

⁵⁸ (Levy Dep. 235:9-24, 294:16-295:7.)

⁵⁹ (Expert Report of Anne McTiernan, M.D., Ph.D. (“McTiernan Rep.”) at 3, Nov. 16, 2018 (attached as Ex. C7 to Tersigni Cert.).)

⁶⁰ (Dep. of Anne McTiernan, M.D., Ph.D. (“McTiernan Dep.”) 46:12-22; 59:10-60:5, 60:15-20, 60:24-61:1, 62:15-23, Jan. 28, 2019 (attached as Ex. B2 to Tersigni Cert.).)

background in gynecological oncology or have not specifically published on the issue of talc and ovarian cancer, the same arguments would apply to Dr. McTiernan.⁶¹

Further, Dr. McTiernan's report goes far beyond her expertise as an epidemiologist and internal medicine physician, offering a host of detailed opinions about the biological mechanisms by which talc purportedly causes ovarian cancer, including opinions that perineally-applied talc is capable of migrating into the vagina and through the genital tract to the ovaries and causing chronic inflammation capable of causing cancer once there.⁶² Dr. McTiernan is not a gynecologist, oncologist, pathologist or cancer biologist and therefore has no relevant qualifications that would allow her to render such opinions.⁶³

Dr. McTiernan also opines that cosmetic talc is capable of causing ovarian cancer because it is contaminated with asbestos, fibrous talc, fragrances and heavy metals such as chromium, nickel and cobalt, but all of these opinions fall far

⁶¹ (See, e.g., Merlo Dep. 19:13-17 (plaintiffs' counsel asking defendants' expert, Dr. Merlo, whether he had experience in gynecology or oncology); *id.* 20:20-21:1 (plaintiffs' counsel asking Dr. Merlo whether he had published on the issues of talc and ovarian cancer); *id.* 150:21-154:10 (plaintiffs' counsel asking Dr. Merlo if he was involved in any epidemiology study about talc and ovarian cancer or if anyone had ever consulted with him about talc and ovarian cancer).)

⁶² (McTiernan Rep. at 58-63, 66-67.)

⁶³ (McTiernan Dep. 61:2-11.)

outside her area of expertise.⁶⁴ Dr. McTiernan concedes that she is not an expert in asbestos, geology, mineralogy, toxicology or industrial hygiene.⁶⁵ She also admitted at deposition that she herself has no knowledge, training or expertise that would allow her to state that cosmetic talc contains heavy metals – but instead bases such opinions on statements made by Dr. Longo, one of plaintiffs’ other experts.⁶⁶ Similarly, Dr. McTiernan relies on statements by Dr. Crowley, another of plaintiffs’ experts, to opine that cosmetic talc contains fragrances and chemicals that are carcinogenic, underscoring that she is not qualified to make such an assessment.⁶⁷ Accordingly, to the extent the Court entertains plaintiffs’ expertise-specific challenges, Dr. McTiernan’s opinions must be excluded as well.

VIII. PATRICIA MOORMAN

Dr. Moorman is an epidemiologist who was retained to “summarize the epidemiologic evidence related to talc use and ovarian cancer risk and to make a judgment as to whether there is sufficient evidence, based on the totality of evidence from epidemiologic investigations as well as laboratory and mechanistic studies, to conclude with a reasonable degree of scientific certainty that talcum

⁶⁴ (McTiernan Rep. at 56-58, 62.)

⁶⁵ (McTiernan Dep. 61:2-11, 252:12-254:16, 266:10-13.)

⁶⁶ (*Id.* 271:25-272:10.)

⁶⁷ (*See* McTiernan Rep. at 58; McTiernan Dep. 272:12-273:16.)

powder use is a causal factor for ovarian cancer.”⁶⁸ Accordingly, Dr. Moorman testified at her deposition that it was her intent to focus her opinions in this proceeding on issues related to epidemiology, which is her particular “area of expertise.”⁶⁹ Yet, Dr. Moorman offers a number of opinions in her expert report that exceed the bounds of her knowledge, experience and training in the field of epidemiology, including discussions of the purported biological mechanisms by which talc migrates to the ovaries and causes cancer there – and the alleged presence of asbestos, heavy metals and fragrances in cosmetic talcum powder.

Most notably, Dr. Moorman opines in her report that “there are biologically plausible mechanisms by which this exposure could lead to ovarian cancer.”⁷⁰ Specifically, she opines that: “(1) talcum powder products can migrate from the perineum through the genital tract to the ovaries and fallopian tubes; (2) talcum powder products can become embedded in the ovarian tissue; (3) talcum powder products can induce an inflammatory response; and (4) the inflammatory response can result in increased oxidative stress and expression of cytokines, mutagenesis, and cell proliferation.”⁷¹ But Dr. Moorman repeatedly admitted at her deposition

⁶⁸ (Expert Report of Patricia G. Moorman, M.S.P.H., Ph.D. (“Moorman Rep.”) at 7, Nov. 16, 2018 (attached as Ex. C35 to Tersigni Cert.).)

⁶⁹ (Dep. of Patricia G. Moorman, M.S.P.H., Ph.D. (“Moorman Dep.”) 60:16-21, Jan. 25, 2019 (attached as Ex. B39 to Tersigni Cert.).)

⁷⁰ (Moorman Rep. at 33.)

⁷¹ (*Id.* at 33-34.)

that these opinions fall outside her area of expertise as an epidemiologist. For example:

- When questioned about whether she conducted a thorough review of the literature related to her biological plausibility opinions, Dr. Moorman insisted that she is “not a cancer biologist” or a “laboratory scientist” and “that is not my major area of expertise.”⁷² Accordingly, she noted that “there is information out there that a cancer biologist would have the expertise to review it in more detail because of their training, which is different than the training and expertise that I have.”⁷³
- Similarly, when asked about the basis for her opinion that perineally-applied talc can migrate to the ovaries, Dr. Moorman admitted that this subject was “a little bit outside [her] area of expertise,” and while her “intent was to read the articles that [she] was aware of, that were brought to [her] attention,” she cannot say whether she conducted a thorough review because of her lack of expertise on the issue.⁷⁴
- While Dr. Moorman seeks to opine that talc causes chronic inflammation that affects the expression of cytokines, mutagenesis, and cell proliferation, she admitted at her deposition that she lacks expertise

⁷² (Moorman Dep. 56:24-57:7.)

⁷³ (*Id.* 57:16-21.)

⁷⁴ (*Id.* 58:25-59:16.)

related to the study of cytotoxicity, genotoxicity or mutagenicity.⁷⁵

Dr. Moorman also admitted that her opinions that “talc products contain additional constituents that are known ovarian carcinogens,” including asbestos, fibrous talc, chromium, nickel and cobalt,⁷⁶ fall outside the scope of her expertise. As

Dr. Moorman concedes, she is not an expert in mineralogy or geology – and the issue of whether cosmetic talc includes asbestos is “a topic that would be more appropriately addressed by a mineralogist.”⁷⁷ Further, Dr. Moorman testified that opinions that cosmetic talc includes heavy metals, fibrous talc or fragrances that are carcinogenic are not based on her own experience or expertise, but are instead dependent on the testimony of other experts.⁷⁸

Thus, Dr. Moorman is not qualified to opine on the biological mechanisms by which talc purportedly migrates to the ovaries and causes cancer there, or on the alleged presence of asbestos, heavy metals and fragrances in cosmetic talcum powder.

⁷⁵ (*Id.* 53:4-12.)

⁷⁶ (Moorman Rep. at 34-35.)

⁷⁷ (Moorman Dep. 65:17-66:3; *see also id.* 82:20-23 (“I am not a mineralogist or a geologist, and so I would not consider myself an expert in reviewing” documents pertaining to whether talc products include asbestos).)

⁷⁸ (*See id.* 118:5-20, 120:2-15, 123:14-124:8; *see also id.* 121:8-122:8; Moorman Rep. at 35 (citing the expert report of Dr. Crowley as the only basis for her opinion that cosmetic talc includes “fragrance ingredients” that are purportedly “harmful to humans”).)

IX. LAURA PLUNKETT

Dr. Plunkett is a litigation pharmacologist who also purports to be a toxicologist.⁷⁹ When asked to describe her role in the MDL proceeding, Dr. Plunkett testified that she was retained to offer opinions regarding toxicology, the regulatory requirements governing cosmetic manufacturers, whether the J&J defendants complied with those requirements, as well as the talc industry's attempt to influence the regulation of talc.⁸⁰ However, the opinions set forth in Dr. Plunkett's report stray well beyond those clearly defined topics, delving into such wide-ranging (and far afield) issues as biological plausibility and the purported presence of asbestos, fibrous talc and heavy metals in talcum powder products.⁸¹ She has never published on any of these topics and is not qualified to opine on them.

Most notably, despite making clear at her deposition that she is "not doing general causation in the MDL,"⁸² her report devotes no fewer than 15 paragraphs to plaintiffs' dubious theory of biological plausibility – i.e., "[t]he migration of talc internally after perineal application" and the "ability of particles to be transported

⁷⁹ (Expert Report of Laura M. Plunkett, Ph.D., D.A.B.T. ("Plunkett Rep.") ¶ 1, Nov. 16, 2018 (attached as Ex. C28 to Tersigni Cert.).)

⁸⁰ (Dep. of Laura Plunkett, Ph.D., D.A.B.T. ("Plunkett Dep.") 33:22-34:9, Dec. 19, 2018 (attached as Ex. B33 to Tersigni Cert.).)

⁸¹ (Plunkett Rep. ¶¶ 17, 24, 27-38.)

⁸² (Plunkett Dep. 33:22-34:1.)

upwards against gravity in the female reproductive tract.”⁸³ That extensive discussion – which is devoted to analyzing various “studies conducted in both humans and in animals”⁸⁴ – is completely divorced from the supposed expertise described by Dr. Plunkett at her deposition. For these reasons, Dr. Plunkett is not qualified to opine on biological plausibility, asbestos or heavy metals.

X. GHASSAN SAED

Dr. Saed claims license to opine on talc and ovarian cancer because he is an “expert in . . . oxidative stress and ovarian cancer.”⁸⁵ Yet, as he admits, he is not “a physician [or an] OB-GYN oncologist who can answer” questions about methods for diagnosing or determining the cause of ovarian cancer because they fall outside his expertise.⁸⁶ Further, he admits that he had never previously performed the type of studies he performed here – i.e., examining the alleged effect of particulate exposure on cells in vitro.⁸⁷ This lack of prior experience directly affected the reliability of his work. For example, as further detailed in defendants’ memorandum in support of their motion to exclude Dr. Saed’s work as unreliable and for lack of fit, Dr. Saed was not aware whether the putative “control” solvent

⁸³ (Plunkett Rep. ¶¶ 43, 55; *see also id.* ¶¶ 41-56.)

⁸⁴ (*Id.* ¶ 55.)

⁸⁵ (Dep. of Ghassan Saed, Ph.D. Vol. 1 (“Saed 1/23/19 Dep.”) 27:10-11, 276:15-17, Jan. 23, 2019 (attached as Ex. B12 to Tersigni Cert.).)

⁸⁶ (*Id.* 248:1-249:12.)

⁸⁷ (*Id.* 27:12-15.)

that he used to dilute talc could have skewed his testing results; he failed to use other particulates as negative or positive controls in his study; and he initially was using amounts of talc so high that he was destroying the cells.⁸⁸ All of these methodological shortcomings can be traced to Dr. Saed's lack of prior relevant experience and highlight that he was unqualified to perform the experiments he undertook on plaintiffs' behalf.

Dr. Saed also expresses opinions that fall outside even his claimed areas of expertise. His report includes opinions on epidemiological studies,⁸⁹ for example, but Dr. Saed is not an epidemiologist – and at his deposition, he admitted that he had never even heard of the Bradford Hill factors before.⁹⁰ Similarly, Dr. Saed expresses a raft of opinions on CA-125 – particularly that increasing levels of CA-125 are an important indicator that talc exposure causes ovarian cancer⁹¹ – even though, as he repeatedly acknowledged at his deposition, he is “not an expert in CA-125.”⁹² This lack of knowledge is especially problematic because, as deposition questioning revealed, Dr. Saed did not even know that CA-125 is

⁸⁸ (See Mem. Of Law In Supp. Of Mot. To Exclude Expert Ops. Of Ghassan Saed at 35-41.)

⁸⁹ (Expert Report of Ghassan Saed, Ph.D. (“Saed Rep.”) at 10-12, Nov. 16, 2018 (attached as Ex. C17 to Tersigni Cert.).)

⁹⁰ (Saed 1/23/19 Dep. 239:10-15.)

⁹¹ (E.g., Saed Rep. at 18, 20.)

⁹² (Saed 1/23/19 Dep. 248:13-249:12.)

correlated with a vast array of conditions that have nothing to do with ovarian cancer, precluding him from assessing possible alternative causes or implications of his in vitro findings.⁹³ For all of these reasons, Dr. Saed's opinions exceed his qualifications.

XI. JACK SIEMIATYCKI

Dr. Siemiatycki is an epidemiologist who candidly does not "pretend to" have sufficient expertise in biological mechanisms to identify or explain the most likely mechanism by which talc would cause ovarian cancer, and who likewise concedes that he is not an expert in the composition of talc, disclaiming knowledge on whether there "are in fact contaminants like asbestos or heavy metals in Johnson & Johnson's talcum powder products."⁹⁴

Yet, he unquestionably attempts to offer opinions in both of these areas. In a section of his report spanning three pages, for example, he discusses the evidence that ostensibly "support[s] a few biologically plausible mechanisms," including the routes that "talcum powder products [ostensibly] can take to reach the ovaries" and the alleged "carcinogenesis [that he claims] can be triggered by the inflammation

⁹³ (See, e.g., *id.* 290:19-25 (unaware whether CA-125 levels can increase during menstrual period or when women have uterine fibroids).)

⁹⁴ (Dep. of Jack Siemiatycki, Ph.D. ("Siemiatycki Dep.") 74:24-75:5, 103:19-104:13, 331:4-25, Jan. 31, 2019 (attached as Ex. B29 to Tersigni Cert.).)

engendered by the particles.”⁹⁵ In connection with inflammation in particular, Dr. Siemiatycki claims that there “is considerable evidence that inflammation is an important mechanism for carcinogenesis,”⁹⁶ despite having conceded that he lacks the expertise needed to conclude that any proposed mechanism is a likely means by which talc would cause ovarian cancer.

Dr. Siemiatycki also includes an entire section of opinions on “[w]hat were women exposed to in body powders?,” which includes a discussion on asbestiform mineral fibers, talc “impurities,” types of asbestos, the “metals detected in talcum powder products” and more.⁹⁷ He further asserts that “[t]he evidence that commercial cosmetic talcum powder products have been shown to contain asbestos, fibrous talc and heavy metals . . . provides a reasonable basis for hypothesizing that these chemicals may contribute to the carcinogenicity of the talcum powder products.”⁹⁸ These opinions exceed Dr. Siemiatycki’s expertise, as he himself conceded at his deposition.

⁹⁵ (Expert Report of Jack Siemiatycki, M.Sc., Ph.D. (“Siemiatycki Rep.”) at 64-66, Nov. 16, 2018 (attached as Ex. C21 to Tersigni Cert.).)

⁹⁶ (*Id.* at 65.)

⁹⁷ (*Id.* at 29-31.)

⁹⁸ (*Id.* at 65-66.) Dr. Siemiatycki’s use of the word “hypothesis” is quite telling because it highlights the speculative nature of plaintiffs’ experts’ testimony with respect to heavy metals, as discussed in more detail in defendants’ Heavy Metals & Fragrances brief, incorporated herein.

XII. SONAL SINGH

Dr. Singh was retained to provide an “opinion about whether talcum powder products are causally related to ovarian cancer” based on his review of the “scientific evidence and . . . epidemiological data.”⁹⁹ But Dr. Singh has no prior experience investigating the relationship between talc and ovarian cancer and has never published on the issue.¹⁰⁰ Thus, to the extent plaintiffs challenge defendants’ experts, including three designated epidemiologists, on the ground that they have not conducted prior research or published articles on this topic, the same arguments would apply to Dr. Singh.¹⁰¹

In addition, Dr. Singh exceeds the scope of his experience by offering detailed opinions regarding the biological mechanisms by which cosmetic talcum powder purportedly causes cancer even though he has no experience in gynecology or oncology.¹⁰² Like many of plaintiffs’ other experts, Dr. Singh seeks to opine that it is biologically plausible for perineally-applied talc to migrate through the genital system to the ovaries (or be inhaled and travel to the ovaries through the lymphatic system), that talc causes chronic inflammation in ovarian tissue and that

⁹⁹ (Expert Report of Sonal Singh, M.D., M.P.H. (“Singh Rep.”) at 3, Nov. 16, 2018 (attached as Ex. C40 to Tersigni Cert.).)

¹⁰⁰ (See Dep. of Sonal Singh, M.D., M.P.H. (“Singh Dep.”) 84:10-17; 85:6-8, Jan. 16, 2019 (attached as Ex. B47 to Tersigni Cert.).)

¹⁰¹ (See, e.g., Moore Dep. 155:12-156:19 (asking defendants’ expert, Dr. Moore, if she had ever published anything on the topics of talc and ovarian cancer).)

¹⁰² (See Singh Rep. at 57-60.)

such chronic inflammation causes cancer.¹⁰³ But when questioned about these opinions at his deposition, Dr. Singh repeatedly conceded that he was not qualified to offer them. For example, Dr. Singh generally admitted that “the biological mechanisms of cancer” are not his “area of expertise” and that this is “an area for other experts.”¹⁰⁴ Indeed, despite dedicating multiple pages of his report to opinions about the mechanism by which talc purportedly moves through the body and causes cancer, Dr. Singh testified at his deposition: “I’m not going to be opining on the precise mechanisms of ovarian cancer in my testimony or my report. That’s not my area of expertise.”¹⁰⁵

Dr. Singh’s report also contains opinions that the “presence of asbestos in talcum powder products can and does provide a plausible biological explanation of the development of ovarian cancer” because “asbestos is a well-established causal agent for the development of . . . ovarian cancer.”¹⁰⁶ Yet, Dr. Singh readily admitted at his deposition that he is not a mineralogist or geologist and does not “have the expertise to determine whether asbestos is present” in the products at

¹⁰³ (*Id.*)

¹⁰⁴ (Singh Dep. 187:3-188:18; 229:14-17.)

¹⁰⁵ (*Id.* 231:16-22; *see also id.* 322:8-17 (“I’m not making this argument that talc is an established mutagen and, you know, whether it’s a genotoxic or nongenotoxic carcinogen. I’m just citing the studies. So, I mean, again, I don’t have that expertise, and, you know, does it provide evidence for or against biological plausibility mechanisms.”).)

¹⁰⁶ (Singh Rep. at 59; *see also id.* at 14-16.)

issue.¹⁰⁷ Dr. Singh similarly conceded that he does not have any specific experience that would qualify him to say that asbestos causes ovarian cancer.¹⁰⁸ In addition, despite stating in his report that “talcum products contain fibrous talc, heavy metals and fragrance ingredients which are known or suspected carcinogens,”¹⁰⁹ Dr. Singh admitted that he cannot establish a “causal link between” these purported constituent ingredients of cosmetic talc and ovarian cancer because he “do[es not] have that area of expertise on individual constituents in products.”¹¹⁰

XIII. REBECCA SMITH-BINDMAN

Dr. Smith-Bindman is a radiologist and epidemiologist who “was asked to review the medical and scientific literature regarding the relationship between genital talcum powder product use and ovarian cancer and determine whether the relationship is causal.”¹¹¹ Prior to becoming involved in this litigation, Dr. Smith-

¹⁰⁷ (Singh Dep. 277:7-8; *see also id.* 279:16-280:2 (Dr. Singh agreeing that mineralogists and geologists are the types of experts that would have substantive knowledge on the issue of whether cosmetic talc contains asbestos, not him).)

¹⁰⁸ (*Id.* 286:15-23 (“Q. What types of asbestos are associated with ovarian cancer? A. I haven’t done a causal analysis of asbestos and ovarian cancer. . . . but -- about asbestos and fibrous talc, but obviously others will provide more -- more specifics”); *id.* 287:3-288:6 (“A. I have not -- as I said earlier, I have not evaluated the specific causal link between asbestos and ovarian cancer.”); *id.* 296:1-5 (“Q. And you’re not making a causal assessment or determination -- A. No. Q. -- on asbestos; is that right? A. Yes.”).)

¹⁰⁹ (Singh Rep. at 60.)

¹¹⁰ (Singh Dep. 299:11-300:12.)

¹¹¹ (Expert Report of Rebecca Smith-Bindman, M.D. (“Smith-Bindman Rep.”) at 4, 6, Nov. 15, 2018 (attached as Ex. C36 to Tersigni Cert.).)

Bindman had not done any work with respect to talc or its purported connection with ovarian cancer.¹¹² Thus, any challenge that plaintiffs may make to the qualifications of defense experts, including epidemiologists, based on their alleged lack of prior experience investigating these topics, would apply to Dr. Smith-Bindman as well.

Further, while Dr. Smith-Bindman indicated at her deposition that she intends to “testify[] . . . as an epidemiologist,” the scope of her opinions goes well beyond the field of epidemiology.¹¹³ Specifically, she seeks to offer opinions regarding biological plausibility, asbestos and heavy metals. She is plainly unqualified to offer these opinions. With respect to biological plausibility, Dr. Smith-Bindman seeks to opine “that particles contained in talcum powder reach the tubes and ovaries, inflammation initiates a causal pathway, and that several components of talc powder products including asbestos, asbestiform fibers in talc, and heavy metals can contribute to the carcinogenicity of the products.”¹¹⁴ She also seeks to opine that it “is clear that talcum powder particles applied to the

¹¹² (Dep. of Rebecca Smith-Bindman, M.D. Vol. I (“Smith-Bindman 2/7/19 Dep.”) 48:14-20, Feb. 7, 2019 (attached as Ex. B40 to Tersigni Cert.) (“Q. You, at least [prior to being retained], had never previously done any research or review relating to talcum powder or relating to any potential association between talcum powder, perineal talcum powder use, and ovarian concern; is that right? A. That’s correct.”).)

¹¹³ (*Id.* 19:18-20, 20:16-18.)

¹¹⁴ (Smith-Bindman Rep. at 40.)

genital region will ascend through the vagina and fallopian tubes and enter the pelvic cavity, reaching fallopian tubes and ovaries.”¹¹⁵ But Dr. Smith-Bindman readily admitted at her deposition that these opinions fall outside of the scope of her expertise. Among other things, she admitted that “the biological processes are not technically epidemiology,”¹¹⁶ and that “there are others who have more expertise directly in [the biological mechanism] area.”¹¹⁷

Dr. Smith-Bindman also seeks to opine that “talcum powder products contain asbestiform talc particles which have a similarity in structure to asbestos fibers (and which IARC concludes are carcinogenic).”¹¹⁸ And she contends that asbestos is “highly carcinogenic” to the lungs, lining of the lungs, larynx and ovaries.¹¹⁹ She further opines on the concentration of asbestos in talc based on “the numbers that [she has] seen.”¹²⁰ But Dr. Smith-Bindman is not a geologist or a mineralogist,¹²¹ and “would absolutely not consider myself an expert on the

¹¹⁵ (*Id.* at 35.)

¹¹⁶ (Smith-Bindman 2/7/19 Dep. 19:18-20, 20:16-18.)

¹¹⁷ (Dep. of Rebecca Smith-Bindman, M.D. Vol. II (“Smith-Bindman 2/8/19 Dep.”) 285:10-17, Feb. 8, 2019 (attached as Ex. B42 to Tersigni Cert.).)

¹¹⁸ (Smith-Bindman Rep. at 5.)

¹¹⁹ (*Id.* at 14.)

¹²⁰ (Smith-Bindman 2/7/19 Dep. 139:22-140:14.)

¹²¹ (*Id.* 141:10-16.)

geology of asbestos.”¹²² She also admits she is not an expert in testing or quantifying the amount of asbestos in a particular product.¹²³

Finally, Dr. Smith-Bindman also seeks to opine that there are heavy metals in defendants’ talc products at levels that can cause cancer.¹²⁴ Yet, she admitted at her deposition that she is “not an expert in understanding [the concentration of heavy metals in talc] in comparison to the concentrations in other things that we’re exposed to” or “how those different concentrations might be expected to have an influence on talc.”¹²⁵

Thus, if the Court considers qualifications challenges, Dr. Smith-Bindman should not be allowed to opine on areas outside her expertise.

XIV. JUDITH ZELIKOFF

Dr. Zelikoff is a toxicologist,¹²⁶ who was asked by plaintiffs’ counsel “to assess biological plausibility in the causation of talc for ovarian cancer.”¹²⁷ But Dr. Zelikoff admits that she only had “superficial” knowledge of talc and ovarian

¹²² (*Id.* 23:1-21.)

¹²³ (*Id.*; Smith-Bindman 2/8/19 Dep. 322:11-17.)

¹²⁴ (Smith-Bindman Rep. at 16.)

¹²⁵ (Smith-Bindman 2/7/19 Dep. 139:7-21.)

¹²⁶ (Expert Report of Judith Zelikoff, Ph.D. (“Zelikoff Rep.”) at 1-2, Nov. 16, 2018 (attached as Ex. C24 to Tersigni Cert.).)

¹²⁷ (Dep. of Judith Zelikoff, Ph.D. (“Zelikoff Dep.”) 72:23-73:16, Jan. 21, 2019 (attached as Ex. B31 to Tersigni Cert.).)

cancer prior to becoming an expert in this litigation.¹²⁸ As she testified, her knowledge was limited to identifying it as a “potential risk factor” in one lecture in a toxicology course, having read media reports and engaging in “lunchroom chatter.”¹²⁹ She had not reviewed any scientific or medical literature regarding talc and ovarian cancer or ovarian cancer etiologies prior to being contacted by plaintiffs’ counsel.¹³⁰ Nor had she published anything regarding talc, cosmetics or ovarian cancer.¹³¹ In addition, despite having dedicated two pages of her report to a discussion of talc, including its chemical structure and particle size, and fibrous talc,¹³² she admitted that she would not consider herself an expert in talc.¹³³ Thus, to the extent plaintiffs challenge the qualifications of any of defendants’ experts on the ground that they do not have a background in talc and ovarian cancer specifically, the same arguments would apply to Dr. Zelikoff.

Dr. Zelikoff seeks to opine that the presence of fragrances and asbestos in talc provides a biologically plausible mechanism for talc to cause ovarian cancer.¹³⁴ For example, she asserts that “a significant number of the fragrance

¹²⁸ (*Id.* 22:10-17.)

¹²⁹ (*Id.* 25:3-19, 30:3-31:15.)

¹³⁰ (*Id.* 141:10-17, 165:1-7.)

¹³¹ (*Id.* 159:5-9, 165:8-12.)

¹³² (Zelikoff Rep. at 3-4.)

¹³³ (Zelikoff Dep. 185:3-13.)

¹³⁴ (Zelikoff Rep. at 5-8, 12.)

chemicals added to talc elicit an inflammatory response.”¹³⁵ She also seeks to opine that “[b]ecause asbestos is a known carcinogen, its presence in cosmetic talc is unacceptable.”¹³⁶ These opinions are far afield from her area of expertise. As Dr. Zelikoff readily admits, she “[has] not been listed as an expert in fragrances” and “[has] not been classified as an expert in asbestos.”¹³⁷ She is not a geneticist, mineralogist, chemist or industrial hygienist.¹³⁸ Prior to submitting her report, she did not read any literature or review any other information regarding the vast majority of fragrances in Johnson’s Baby Powder or Shower to Shower.¹³⁹ Instead, the brief discussion of fragrances in her report is based entirely on her adoption of the expert report of Dr. Crowley, belying any claim that she has relevant knowledge or expertise on this subject.¹⁴⁰ Moreover, Dr. Zelikoff could not identify a single article that she authored regarding asbestos.¹⁴¹ Nor has she done

¹³⁵ (*Id.* at 12.)

¹³⁶ (*Id.* at 6.)

¹³⁷ (Zelikoff Dep. 178:8-9; 184:1-6.)

¹³⁸ (*Id.* 185:20-187:1.)

¹³⁹ (*Id.* 45:19-48:9.)

¹⁴⁰ (Zelikoff Rep. at 12; Zelikoff Dep. 48:4-9 (Dr. Zelikoff conceding that, prior to submitting her report, she did not look at any of the source material cited in Dr. Crowley’s expert report).)

¹⁴¹ (Zelikoff Dep. 163:2-8.)

any professional work regarding asbestos.¹⁴² Accordingly, she also lacks the qualifications to offer the fragrance- and asbestos-related opinions in her report.

CONCLUSION

While defendants do not believe that challenges to expert qualifications are a good use of the Court's or parties' resources, defendants conditionally request that the Court exclude the above-referenced opinions offered by plaintiffs' experts on qualifications grounds to the extent it entertains plaintiffs' anticipated arguments with respect to the qualifications of defendants' experts.

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Respectfully submitted,

/s/ Susan M. Sharko

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¹⁴² (*Id.* 169:11-15.)